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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,533

09/01/2006

Yoshinobu Yamazaki

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EXAMINER

BLAKELY III, NELSON CLARENCE

ART UNIT

PAPER NUMBER

1629

NOTIFICATION DATE

DELIVERY MODE

04/01/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/598,533	<b>Applicant(s)</b> YAMAZAKI ET AL.	
	<b>Examiner</b> NELSON BLAKELY III	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Application Status***

Claims 1-12 of the instant application are pending. Claims 4, 5 and 7-12 are withdrawn pursuant to Applicant's Amendment, filed 11/30/2010. Accordingly, instant claims 1-3 and 6 are presented for examination on their merits.

Applicant's Arguments, filed 11/30/2010, have been fully considered. Rejections/objections not reiterated from previous Office Actions are hereby **withdrawn**. The following rejections/objections are either reiterated or newly applied. They constitute the complete set of rejections/objections presently being applied to the instant application.

### ***Information Disclosure Statement***

In the previous Office action, the two NPL references, i.e., Teruhisa Ohashi and Osamu Ishizuka, on the IDS, filed 03/12/2007, were not considered because the references failed to disclose, at least, an abstract in English.

### **Applicant's Arguments**

Applicant alleges the Examiner in error. Applicant further alleges that the International Preliminary Report on Patentability (Chapter I) with a written opinion of the International Searching Authority, received 12/22/2006, provides a concise explanation of the relevance of the two NPL references, which are in Japanese.

### **Examiner's Response**

Applicant's arguments, filed 11/30/2010, have been fully considered, but they are not persuasive. It is noted the Information Disclosure Statements, filed 03/12/2007, 01/13/2009 and 02/26/2009, fail to list the aforementioned International Preliminary Report on Patentability, which would have been considered by the Examiner. Instead, however, that Statement, filed 03/12/2007, lists the aforementioned NPL references that were previously not considered. See reason set forth *supra*. Pursuant to the MPEP, specifically 37 C.F.R. § 1.98, the Examiner has considered, and submitted herewith, English-language translations of the aforementioned non-English language references.

#### ***Applicant's Amendment***

Applicant's Amendment, filed 11/30/2010, wherein the specification and claims 1-12 are amended, and claims 4, 5 and 7-12 are withdrawn, is acknowledged.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shimoyama *et al.* (European Patent Application No. EP1358889A1; cited by Applicant), in view of Garvey *et al.* (U.S. Patent Application Publication No. 2002/0143007A1; cited by Applicant).

#### **Applicant's Arguments**

Applicant alleges that there is no disclosure about the efficacy of other  $\alpha$  receptor blockers on the urinary disturbance due to (2) abnormality of urination-controlling nerve in Shimoyama *et al.* Further, with regard to PCT/JP99/03343, or the English language translation EP1088551, as recited by Shimoyama *et al.*, Applicant alleges no disclosure or suggestion regarding the storage dysfunction, such as urinary urgency, is provided. With regard to Garvey *et al.*, Applicant alleges that there are no experimental data on overactive bladder.

Examiner's Response

Applicant's arguments, filed 11/30/2010, have been fully considered, but they are not persuasive.

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In summation, Shimoyama *et al.* disclose, in reference claim 4, page 10, a method for the therapy of lower urinary tract symptoms, wherein said method includes administration of an  $\alpha_1$  receptor blocker to a patient. In paragraph [0015], page 3, Shimoyama *et al.* disclose wherein "lower urinary tract symptoms" refer to (3) symptoms of urinary disturbance due to a functional obstruction of lower tract of both males and females, and do not include that which is due to disturbance of nerve controlling the lower urinary tract. Shimoyama *et al.* disclose, in paragraphs [0002] through [0006], page 2, there are various causative diseases for the urinary disturbance, such as (1)

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organic obstruction of urethra, e.g., benign prostatic hyperplasia (or hypertrophy) and (2) abnormality of urination-controlling nerve (generally called neurogenic bladder), e.g., cerebrovascular accident, myelopathy (spina bifida, tethered cord syndrome), multiple sclerosis and spinocerebellar degeneracy. In paragraphs **[0017]** and **[0018]**, page 3, Shimoyama *et al.* disclose wherein the  $\alpha_1$  receptor blocker may be, preferably, KMD-3213, or (-)-1-(3-hydroxypropyl)-5-((2R)-2-[[2-[(2,2,2-trifluoroethyl)oxy]phenyl]oxy)ethyl]amino}propyl)-2,3-dihydro-1H-indol-7-carboxamide.

Additionally, Garvey *et al.* disclose, in the Abstract, methods for treating benign prostatic hyperplasia (or hypertrophy), neurodegenerative disorders, urge incontinence or overactive bladder, wherein the  $\alpha$ -adrenergic receptor antagonist is KMD-3213. See also reference claims 37, 38, 52 and 58. Accordingly, one of ordinary skill in the art, at the time of the invention, would have envisaged a method of treatment of overactive bladder accompanied with a spinal cord involvement, comprising the administration of KMD-3213, as disclosed by Shimoyama *et al.*, in view of Garvey *et al.*

With regard to Shimoyama *et al.*, a reference may be applied not only for what it expressly teaches by direct anticipation, but also for what one of ordinary skill in the art, at the time of the invention, might reasonably infer from the teachings. See *In re Opprecht*, 12 USPQ 2d, 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). In light of the foregoing, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a). Accordingly, though Shimoyama *et al.* define “lower urinary tract symptoms” as category

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(3), an artisan would have construed another causative disease for urinary disturbance, e.g., categories (1) and (2).

With regard to Garvey *et al.*, a preferred or exemplified embodiment does not constitute a teaching away from other embodiments disclosed within the four corners of the reference, including non-preferred embodiments. Applicant is reminded that the disclosure of a reference must be considered as expansively as is reasonably possible to determine the full scope of the disclosure and, as a result, is most certainly not limited to that which is preferred and/or exemplified. Thus, the fact that other methods may be exemplified, claimed and/or preferred does not negate or direct the artisan away from the broader teaching of the reference, which expressly provides for, and, thus, clearly contemplates the use of KMD-3213, a compound of identical structure to those within the genus of compounds instantly claimed. The fact that the reference may teach embodiments that differ from Applicant's own invention does not negate, or teach away from, the teachings of the reference as a whole and what the reference as a whole would have reasonably suggested to one having ordinary skill in the art at the time of the invention. Accordingly, the rejection is ***maintained***.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to NELSON BLAKELY III whose telephone number is (571)270-3290. The Examiner can normally be reached on Mon - Thurs, 7:00 am - 5:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jeffrey S. Lundgren can be reached on (571) 272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phyllis G. Spivack/  
Primary Examiner, Art Unit 1614  
March 27, 2011

/N. B. III/  
Examiner, Art Unit 1614